



Health Protection Agency, Porton Down
and
European Collection of Cell Cultures

This document certifies that
Virus RAdEs
Deposit Reference 04121701

has been accepted as a patent deposit, in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on
17 December 2004

Dr D H Lewis
General Manager
ECACC

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

To: DR. S. PRATI
NATIONAL INSTITUTE OF IMMUNOLOGY
VETERINARY LABORATORY

NEW DELHI
110 067
INDIA

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the
DEPOSITOR:
RAGE8

Accession number given by the
INTERNATIONAL DEPOSITORY AUTHORITY:
04121701

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

- ☒ A scientific description
☐ A proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above,
which was received by it on 17 December 2004 (date of the original deposit)

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International
Depository Authority on (date of the original deposit) and
A request to convert the original deposit to a deposit under the Budapest Treaty
was received by it on (date of receipt of request for conversion)

V. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis

Address: ECACC
HPE
Porton Down
Salisbury SP4 0QG

Signature(s) of person(s) having the power
to represent the International Depository
Authority or of authorized official(s):

Date: 27/1/05

Where Rule 6.4(3) applies, such date is the date on which the status of international depository
authority was acquired

Form BP/4 (sole page)

1991

BUDPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

DR. S. VRATTI
NATIONAL INSTITUTE OF IMMUNOLOGY
VIROLOGY LABORATORY

VIABILITY STATEMENT
Issued pursuant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

DATE PRINTED
17 DEC 2004
11:18

NAME AND ADDRESS OF THE PARTY
BY WHICH THE VIABILITY OF STATEMENT
IS ISSUED

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
<p>NAME: DR. S. VRATTI NATIONAL INSTITUTE OF IMMUNOLOGY VIROLOGY LABORATORY</p> <p>Address: NEW DELHI 110 067 INDIA</p>	<p>Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: 04121701</p> <p>Date of the deposit or of the transfer: 17 December 2004</p>

III. VIABILITY STATEMENT	
<p>The viability of the microorganism identified under II above was tested on 17 December 2004¹. On that date, the said microorganism was</p> <p><input checked="" type="checkbox"/> ² viable</p> <p><input type="checkbox"/> ³ no longer viable</p>	

Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer):

In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.

Mark with a cross the applicable box.

Form BPA (first page)

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED ⁴

The Virus Accession Deposit ARDS Accession Number 04121701 was tested according to the depositor's protocol and shown to be infectious and viable.

II. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr D H Lewis
 Address: ECACC HPA
 Porton Down
 Salisbury
 Wiltshire
 SP4 0JG

Signature(s) of person(s) having the power
 to represent the International Depositary
 Authority or of authorized official(s):

Date: 27/1/05

Fill in if the information has been requested and if the results of the test were negative.

Form BP/9 (second and last page)

Patent Deposit Accession Form

Virus

DEPOSITOR INFORMATION

Name of Depositor/Company/Institute NATIONAL INSTITUTE OF IMMUNOLOGY

(NB this will be the name that appears on certification)

Contact Name DR. SUDHANSHU VRATI

Depositor Address NATIONAL INSTITUTE OF IMMUNOLOGY, NEW DELHI-110067

Tel No +91-11-26703696 Fax No +91-2-26162125 Email vrati@nii.res.in

BIOHAZARD STATEMENT MUST BE ENCLOSED

The deposit is made in accordance with the terms of the Budapest Treaty 1977. I agree to abide by the conditions and regulations regarding the deposit of cell lines to the ECACC.

Signature [Signature] Date 16-JUNE-2004

Address to which invoice should be sent (if different from above)

DIRECTOR
NATIONAL INSTITUTE OF IMMUNOLOGY
NEW DELHI-110067

VIRUS INFORMATION

Name in full Recombinant Human adenovirus

Abbreviated Name RADES Identification on Ampoules RADES

Strain Serological Type

Normal Host

Virus Titre Deposited

VIRUS PROPAGATION

Host cells (first choice) Human embryonic kidney 293 cells

Alternative Host Cells None

Details of Host Cell Growth (media, temperature, seeding density, growth factors etc) Grown in 10% monolayers of
HEK 293 cells cultured in DMEM+10% FCS

Details of Virus Growth (eg confluency of host cells, co-cultivation, moi, effects, time taken) At moi 0.1 it takes ~36 hr
for CPE to appear. cells are then harvested & virus prepared.

VIRUS STORAGE

Material stored (eg supernatant, infected cell extract, viable infected cells etc)

Temperature and conditions Infected cell extract, to be stored at -70°C

VIRUS ASSAY

Method (enclose if necessary) Plaque assay on 293 cells.

LITERATURE REFERENCES (if any)

ANY OTHER RELEVANT INFORMATION

Please Note: ECACC must receive full information regarding delivery at least 48 hours before despatch.

A Biohazard Risk Assessment must be completed in order for your samples to be accepted. ECACC is required to assess the GMO status of all deposits PRIOR to receipt. Therefore, we will contact all depositors to advise them when we can receive samples.

2. Does the GM agent contain/produce a biologically active substance that could potentially cause harm to humans (eg toxin, cytokine, hormone, allergen, oncogene)

Yes ☐

No ☒

3. What is the likelihood that the genetic modification can confer pathogenic traits in the host organism?

Negligible	Possible	Probably or Demonstrated
✓		

If "possible", "probably" or "demonstrated" please provide additional details:

.....

4. What is the potential for sequences within the GM being transferred to another related microorganism?

Negligible	Low	Medium	High
✓			

If "medium" or "high" please provide additional details:

.....

5. In the light of your knowledge of this GMM and its origination, what is your assessment of its potential to cause harm to human health in the event of exposure?

Negligible	Low	Medium	High

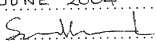
If "medium" or "high" please provide additional details:

.....

6. Does this GMM have the ability to survive, establish and disseminate in the environment?

Yes ☐

No ☒

Form completed by: Name: DR. SUDHANSHU VRATI
Title: STAFF SCIENTIST
Date: 16TH JUNE 2004
Signature: 
All details above are correct

ECACC may request further information in order to complete its risk assessment. To whom should such requests be addressed?

Name: DR. G.W. BOTH
Telephone: +61-2-9490 5169
Fax: +61-2-9490 5005
E-mail: Gerry.Both@csiro.au

Biohazard Risk Assessment

To be completed prior to acceptance of a biological agent into an ECACC repository

For ECACC use only

Type of Deposit:

Accession Number:

Depositor Code:

Activity Class:

Signed: Date:

For Completion by Depositor

The Biological Agent is:

Animal Cell ☐ Virus ☒ Bacterium ☐ Yeast ☐ Plasmid ☐

Genetically Modified ☒ If yes. What Class: Category 1

If you have answered Class 2 or above please forward to us any Risk Assessment you have carried out yourselves relating to this deposit.

Other (please define):

Species: Replication - defective human adenovirus

Strain: type 5

Identification Code: RAdEs

ACDP Hazard Group¹ 1 ☒ 2 ☐ 3 ☐ 4 ☐ If USA deposit use SALS Category

Does this require a Specified Animal Pathogens Order YES/NO

If yes please refer to the DEFRA Web site for a licence application. www.defra.gov.uk

Brief description of deposit. If the agent is genetically modified include details of inserted gene, method/vehicle for insertion and any expression product.

E1 transcription unit-deleted, replication-defective human Adenovirus (Ad) 5 was modified to contain in its genome, the cDNA encoding Japanese encephalitis virus (JEV) prM and E proteins under the control of the Cytomegalo virus promoter in place of the E1 transcription unit. The recombinant virus RAdEs, thus generated, is unable to replicate in mammalian cells other than HEK293 where Ad5 E1 transcription unit has been integrated permanently. RAdEs is capable of expressing JEV prM and E proteins in mammalian cells.

To be completed if the biological agent is genetically modified

¹ ACDP Advisory Committee on Dangerous Pathogens

Hazard Group 1 A biological agent unlikely to cause human disease.

Hazard Group 2 A biological agent that can cause human disease and may be a hazard to employees, it is unlikely to spread to the community and there is usually effective prophylaxis and effective treatment available.

Hazard Group 3 A biological agent that can cause severe human disease and presents a serious hazard to employees. It may present a risk of spreading to the community, but there may be a prophylaxis or treatment available.

Hazard Group 4 A biological agent that causes severe human disease and is a serious hazard to employees. It is likely to spread to the community and there is usually no effective prophylaxis or treatment available.



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